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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,909	11/16/2001	Joan M. Fallon	8016-5	3427

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F. Chau & Associates, LLP
Suite 501
1900 Hempstead Turnpike
East Meadow, NY 11554

EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	13

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,909	FALLON, JOAN M.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7 and 21-29* is/are pending in the application.

4a) Of the above claim(s) *22-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 7, and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *February 25, 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Request for Information* .

DETAILED ACTION

Status of the Claims

1. Claims 1, 2, 7, and 21-29 are pending in the present application. Claims 22-29 are withdrawn as to non-elected inventions, and claims 1, 2, 7, and 21 are under consideration. Claims 1, 2, and 7 are under consideration only to the extent that they read on the elected invention (wherein the PDD is autism). This action is in Response to the Amendment (and appurtenant election), and Declaration filed on February 7, 2003.

2. In view of the changes to the claimed methods, all prior art rejections are withdrawn. However, the enablement rejection of the prior claims is maintained with regards to amended claims 1, 2, and 7, and extended to new claims 21 and 24. All rejections are withdrawn as to claims 3-6, now cancelled.

3. This action is being made Non-Final because it raises issues not raised in the prior action, and not necessitated by amendment. Further, in addition to this action, the Applicant will find an attached Requirement for Information for which a response is required in a complete reply to this action.

Election/Restrictions

4. Claims 22-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

5. Applicant's election with traverse of Group I (A) in Paper No. 12 is acknowledged. The traversal is on the ground(s) that there is no undue burden in searching the various claimed inventions because all of the inventions fall within the same class and subclass. This is not found persuasive because the separate inventions each relate to the diagnosis of a different disease. Although the various methods all share similarities in their operation bringing them under the same class and subclass heading, this does not demonstrate that there is no burden in examining the various inventions together. Because each of these inventions relates the diagnosis of a separate disease or disorder, they each require searches not required for the other inventions. As such, there is a burden in the examination of all of the claimed inventions.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

6. New corrected drawings are required in this application because in Figure 2, the figure has misspellings of the work "Parkinson" for both patients 5 and 15. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities: the specification is objected to because, in the description, on page 12-13, the application indicates that 19 children diagnosed with autism were found to have a plurality of infections. However, the Figure to which the specification refers (Figure 4) shows only 13 patients, the results of each of these 13 patients corresponding exactly to the results indicated for the 13 patients identified as having ADD or ADHD in Figure 3. Thus, the teachings in the specification do not correspond with the teachings in the Figure referred to.

Appropriate correction is required.

Claim Objections

8. Claim 21 is objected to because of the following informalities: the claim limits the method of claim 1 to embodiments wherein "the PPD is autism." The term "PPD" should be --PDD--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(New Rejection) Claims 1, 2, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims describe methods of determining if a person has a pervasive development disorder (PDD). The application provides no definition for what is

included within the class of disorders identified as PDDs. However, the claims indicate that both ADD and autism are PDDs, whereas the specification, on page 10 at lines 7-9, lists both ADD and ADHD as separate from PDDs. Furthermore, the art does not appear to consider ADD and ADHD as PDDs. See e.g., MESH Browser (classifying Attention Deficit Disorders separately from the Pervasive Child Development Disorders); and Johnson et al., U.S. Patent 6,210,950 (indicating at column 3, lines 21-29, that autism is a PDD, and that ADHD is an Attention-Deficit and Disruptive Behavioral Disorder). Thus, the Applicants claims are inconsistent with the written description, and with what appears to be meaning of PDDs within the art.

It is noted that the Applicant may act as their own lexicographer. However, when the Applicant acts as such, and applies a particular meaning to a term used otherwise in the art, the meaning assigned by the Applicant "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." MPEP § 2111.01 (quoting Multiform Desiccants Inc. v. Medzam Ltd., 45 USPQ2d 1429, 1432 (Fed. Cir. 1998)). In the instant case, the Applicant has not provided a specific definition by which one skilled in art could identify disorders considered by the Applicant as PDDs. Nor has the Applicant specifically identified all of the disorders considered to be PDDs, or, apparently, used the term PDD as it is used in the art. In view of this, those skilled in the art have not been made aware of what the Applicant considers to be a PDD, and therefore would not be able to identify the metes and bounds of the claimed invention. The claims are therefore rejected as indefinite.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior Rejection-Restated)** Claims 1, 2, 7, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of determining if a person has autism, does not reasonably provide enablement for methods of determining if a person can develop such a disorder. The claims describe a method of diagnosing autism, and PDDs, through the claimed method of determining the presence of multiple pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 1, 2, and 7 were rejected on this basis, among others, in the action mailed on July 30, 2002. In that action, the Examiner stated, in relevant part, as follows:

> Secondly, the applicant has not shown that the detection of a pathogen in a stool sample is predictive of any of the claimed disorders. For example, although the art has noted that Helicobacter pylori has been associated with neurological diseases (see, Tsang, HKMJ, 5:169-174); neither the art nor the applicant has shown that indications of H. pylori in a stool sample would lead one in the art to believe that every person so infected either has, or is going to develop, a neurological disease. See e.g., Dobbs et al, Medical Hypothesis 55:93-98, at 96 (indicating that while H. pylori infections may be causative for some instances of Parkinson's disease, Parkinson's is not universally associated with the infection). In order for the applicant to enable such a claim, the applicant must show not just a correlation between the pathogen and the disease in general, but a correlation between a pathogen, and the development of the disease. This is because correlations can exist in the absence of any real predictive relationship. See e.g. Woodward et al., Gut 43:285-287 (indicating a correlation between Clostridium difficile and dysautonomia in that the infection was tested for, but not indicating that the infection has any predictive or causative relation to dysautonomia). In short, the applicant must show that the correlation between those who test positive for the pathogen, and those who have the claimed disorder is not merely allegorical, but has real potential as a diagnostic tool.
>
> In the specification, the applicant does show that individuals with the claimed disorders tend to have infections by multiple pathogens. See,

> specification, pp. 11-13. However, the applicant has not shown that these infections have a causal relationship with any of the identified diseases. The children tested all already had the disorders. The applicant did not show that children with the disclosed infection were likely to develop the disorder. In order to do so, the applicant would need to show that a percentage of people with the disclosed infections were more likely to develop the diseases than those not infected. The applicant has not shown the percentage of people with infections have developed the disclosed diseases or disorders. Rather, the applicant has only shown that those with the disclosed disorders are more likely than healthy persons to have multiple infections, but have not shown that any one infection is likely to indicate one of the claimed disorders. This is true both for the generic claim, and for the elected pathogen of claim 7, Helicobacter pylori.

As indicated in the excerpt, while the Applicant has demonstrated that the presence of a plurality of different pathogens is indicative of the presence of a PDD, there has been no showing that such a presence is predictive of PDDs. The statistical data and conclusions of the Applicant, as indicated both in the application, and the Declaration, have been considered. But none of the data demonstrates either the presence of, or a causal role for, such multiple infections prior to the development of the disorder.

In view of this lack of data, and for substantially the same reasons as indicated in the prior action with respect to the previously claimed inventions, the Applicant is not enabled for a method of determining if a person is likely to develop a PDD based on the presence of antigens to multiple pathogens in the person's stool. Because new claim 21 merely recites a specific PDD, and is dependant on claim 1, the rejection is extended to this claim

(New Rejection) Claims 1, 2, and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on methods of determining if a person has a PDD based on the presence of a plurality of pathogenic infections. However, the Applicant has not provided a clear definition of what a PDD is. Because the Applicant has not set forth a clear indication of what is being claimed, the Applicant has not provided adequate written description of the claimed invention.

In its discussion of the written description requirements of 35 U.S.C. § 112, the MPEP stats as follows:

> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

MPEP § 2111.01, (quoting Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d at 1116). Later, with reference to claims found in the original application, the MPEP also states:

> However, as discussed in paragraph I., supra, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art.

MPEP § 211.01 A. Thus, in order have adequately described the claimed invention, the Applicant must have provided such a description that those skilled in the art would recognize what is being claimed.

In the specification, the Applicant has described PDDs as including ADD, ADHD, and autism. Page 2, lines 1-3, and claims 1, 22, and 23. However, the Applicant has also provided

lists where ADD and ADHD were apparently considered separate from PDDs. Page 10, lines 7-9. Furthermore, the art surrounding the claimed invention also appears to classify ADD and ADHD as distinct from PDDs. See e.g., MESH Browser (classifying Attention Deficit Disorders separately from the Pervasive Child Development Disorders); and Johnson et al., U.S. Patent 6,210,950 (indicating at column 3, lines 21-29, that autism is a PDD, and that ADHD is an Attention-Deficit and Disruptive Behavioral Disorder). Thus, the application contains conflicting indications as to what comprises a PDD. Further, and the interpretation apparently intended by the Applicant is in conflict with the art. Thus, the Applicant has not clearly described the invention to such an extent that those in the art would understand what the Applicant was in possession of. This is because the Applicant has not clearly defined what the Applicant means by a PDD. Because those skilled in the art have not been appraised of what it is that the Applicant is claiming, the Applicant has not provided adequate written description for the claimed invention.

12. **(New Rejection-Necessitated by Amendment)** Claims 1, 2, 7, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while apparently being enabling for diagnosing autism, by detecting the presence of antigens from a plurality of pathogens listed, for example, in Figure 3 or on page 9 of the application, does not reasonably provide enablement for methods of such diagnosis by detecting antigens of plurality of other pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The identified claims read on methods of diagnosing a person with, or determining that a person is likely to develop autism. According to the claimed invention, the detection of any

plurality of pathogens is indicative of the identified disorder. In support of these claims, the Applicant has demonstrated an association between certain PDDs, including autism, and certain pathogenic infections. See e.g., App., Figure 3, and page 9, and the Declaration, pages 1-5 (each listing a particular set of pathogens with which the identified disorder has been associated). However, the Applicant has not shown that the detection of any set of pathogens would be indicative of the identified diseases or disorder. Nor has the Applicant provided any guidance as to what other pathogens may be associated with the disorders.

Further, the existence of multiple diseases associated with a plurality of pathogens is acknowledged in the art. See e.g., U.S. Patent 5,436,319, col. 12, lines 60-68(acknowledging the existence of diseases associated with multiple pathogens). See also, Ganz et al., U.S. Application Publication 2003/0097122, pages 5-6, paragraphs 0057 and 0058 (indicating that the bacterium Porphyromona gingivalis may be one of a plurality of bacterium that may be associated with coronary artery disease, but that has not been shown to be indicative of PDD in the present application); and U.S. Patent 6,482,839, col. 4, lines 23-29 (indicating that the disorder Folliculitis is a disease that may be characterized by a different set of pathogens than those in the present application). Thus, the existence of other diseases that may be diagnosed by the presence of multiple pathogens, including pathogens not identified by the Applicant, is known.

It is noted that claim 7 limits the claimed methods of diagnosing PDD to instances wherein one of the pathogens is H. pylori. However, this alone does not appear sufficient to distinguish PDD from other disorders as this pathogen has associations with a number of diseases and disorders. See e.g. Ganz, supra, at page 1, paragraphs 0005 and 0006; and Koster et al., Acta Gastro-Enterologica Belgica 63: 388-92, page 389, left column, first paragraph.

Because of the diverse associations of this bacterium, the Applicant is not enabled for a method of diagnosing a PDD by detecting any plurality of pathogens wherein one of the pathogens is H. pylori. The Applicant has shown only that s plurality of pathogens from a specific set of pathogens, one of which may by H. pylori, is indicative of PDD.

Because the Applicant has identified only limited set of pathogens, a plurality of which may be indicative of a PDD, and because a plurality of pathogens other than those identified in the application may be indicative of a disease or disorder other than a PDD, the Applicant is not enabled for the full scope of the claimed invention.

13. **(New Rejection-Necessitated by Amendment)** Claims 1, 2, 7, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on methods of determining the susceptibility of a person, or diagnosing a person with, a PDD by detecting a multiplicity of pathogenic infections in a person.

These claims read on embodiments wherein the multiplicity of pathogens may be any set of pathogens, or any set of pathogens wherein one of the pathogens is H. pylori. However, while the Applicant has demonstrated an association between certain PDDs and a number of specific pathogens, they have not established that these disorders may be associated with any combination of pathogens. As indicated above, there are other disorders that are associated with

a multiplicity of pathogenic infections. Thus, the detection of a particular set of pathogens may be indicative of one, but not another of such disorders.

Also, in the application, the Applicant has demonstrated a number of specific pathogens with which PDDS may be associated. However, the application neither indicates how these pathogens are associated with the disorders, nor provided any other guidance that would lead one of ordinary skill in the art to identify other such pathogens. The fact that the Applicant has identified a few specific pathogens that are associated with autism does not support claims to methods of diagnosing autism with any set of pathogens. For example, Finegold et al. (CID 35(Suppl): S6-16) discloses a number of other pathogens that may be found in autistic patients. Of these pathogens, only 2 fall within the groups identified by the Applicant. See, Finegold, page S10, Table 2, (identifying two species of Campylobacter as being present in one patient with autism). None of the remaining pathogens listed in the reference have been identified in the present application. Nor is there any guidance that would lead those in the art to such other pathogens. Thus, the teachings of the present application identify only a specific set of pathogens, the presence of a plurality of which may indicate that the patient has autistic disorder.

In view of the knowledge of the art that a multiplicity of pathogenic infections may be indicative of several diseases, and the lack of guidance towards other pathogens that may be indicative of PDDs, or autism in specific, the Applicant has not provided sufficient written description support for the full scope of the claimed invention.

Conclusion

14. No claims are allowed.

15. This Office action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
July 21, 2003

James C. Housel 7/28/03
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Requirement for Information

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

It is noted that the data provided in Figures 3 and 4, although indicating that the data was collected from two different populations of patients, correspond exactly to each other (at least with reference to the 13 patients indicated as having ADD or ADHD in Figure 3). It is further noted that the part of the specification (pages 12-13, case 4) indicating what information may be found in Figure 4 is not consistent with respect to the number of patients tested found in the Figure. An explanation of the inconsistency between the written description and the data provided in the Figure is required. Also required is an explanation for the exact replication of patient age and infection data provided for the patients in Figures 3 and 4, although the patients supposedly represent two different populations.

2. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete reply to the requirement for that item.

3. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.